51	STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2017-18) SIXTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations contained in the Forty Fifth Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on 'Demands for Grants 2018-19' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

FIFTY-FIRST REPORT

LOK SABHA SECRETARIAT
NEW DELHI

JULY, 2018 /SHRAVANA, 1940 (SAKA)

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(2017-18)

(SIXTEENTH LOK SABHA)

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(DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on the Observations / Recommendations contained in the Forty Fifth Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on 'Demands for Grants 2018-19' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

Presented to Lok Sabha on 31 July, 2018

Laid in Rajya Sabha on 31 July 2018

LOK SABHA SECRETARIAT
NEW DELHI
JULY, 2018 /SHRAVANA, 1940 (SAKA)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2017-18)

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri George Baker
3. Smt. Anju Bala
4. Shri B.N. Chandrappa
5. Shri Pankaj Chaudhary
6. Shri Sankar Prasad Datta
7. Dr. Ratna De Nag
8. Smt. Veena Devi
9. Shri R.Dhruvanarayana
10. Shri Innocent
11. Prof. A Seetaram Naik #
12. Shri K. Ashok Kumar
13. Shri Chhedi Paswan
14. Smt. Kamla Devi Patle
15. Shri Rajendran S.
16. Dr. Kulamani Samal
17. Dr. Uma Saren
18. Dr. Krishna Pratap Singh
19. Shri Kirti Vardhan Singh
20. Smt. Rekha Arun Verma
21 Shri Sarfaraz Alam*

RAJYA SABHA

22. Shri Biswajit Daimary
23. Shri Prem Chand Gupta
24. Shri B.K. Hariprasad
25. Shri Vijay Pal Singh Tomar@
26 Shri Ranvijay Singh Judev
27. Dr. Sanjay Sinh
28. Shri Abdul Wahab
29. Shri Sanjay Dattatraya Kakade
30. Vacant^
31. Vacant^

SECRETARIAT

1.	Shri Vinod Kumar Tripathi	Joint Secretary
2.	Shri A. K. Srivastava	Director
3.	Shri U. C. Bharadwaj	Deputy Secretary
4.	Ms. Sonia Sankhla	Committee Assistant

 # Prof. A. Seetaram Naik MP, (LS) has been nominated as a Member of the Committee on Chemicals and Fertilizers w.e.f. 3.11.2017 vice Shri Kotha Prabhakar Reddy MP, (LS) who ceased to be a Member of the Committee on Chemicals and Fertilizers w.e.f. 3.11.2017

**Shri Sarfaraz Alam has been nominated as a Member of the Committee on Chemicals and Fertilizers w.e.f. 27.04.2018*

@Shri Vijay Pal Singh Tomar has been nominated as a Member of the Committee on Chemicals and Fertilizers w.e.f. 02.06.2018

^Vacant vice Dr. Bhusan Lal Jangade due to his retirement from Rajya Sabha on 02.04.2018.

^Vacant vice Shri K. Parasaran due to his retirement from Rajya Sabha on 28.06.2018.

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2017-2018) having been authorised by the Committee to present the Report on their behalf, present this Fifty-first Report (Sixteenth Lok Sabha) on Action Taken by the Government on the observations/ recommendations contained in the Forty-fifth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2017-18) on Demands for Grants 2018-19 pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

2. The Forty-fifth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on **13.03.2018**. The Action Taken replies of Government to all observations / recommendations contained in the Report were received on 14.06.2018 The Standing Committee on Chemicals and Fertilizers (2017-2018) considered and adopted this Report at their sitting held on 23.07.2018.

3. An analysis of the Action Taken by the Government on the observations/recommendations contained in the Forty-fifth Report (Sixteenth Lok Sabha) of the Committee is given in **Appendix-II.**

4. For facility of reference and convenience, the Comments of the Committee have been printed in bold letters in the body of the Report. - **Chapter-I**

New Delhi;
27 July, 2018
05 Shravana 1940 (Saka)

ANANDRAO ADSUL
Chairperson
Standing Committee on
Chemicals and Fertilizers

REPORT

CHAPTER I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Forty Fifth Report (Sixteenth Lok Sabha) of the Committee on the Demands for Grants 2018-19 of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 13.03.2018. In all, the Committee made 9 Observations / Recommendations in the Report.

2. Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the Forty Fifth Report within three months from the date of presentation of the Report, i.e., by 12.06.2018. The Action Taken Replies of the Government in respect of all the 9 Observations/ Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their O.M. No. 23003/1/2018-IFD dated 12.06.2018. These Replies have been categorized as follows:-

(i) Observations / Recommendations that have been accepted by the Government :-

Sl. Nos. 1, 3, 5,7, 8 (Total=5)

These may be included in Chapter II of the Draft Report.

(ii) Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply :-

Sl. No. 9 (Total = 1)

This may be included in Chapter III of the Draft Report.

(iii) Observations / Recommendations in respect of which replies of the Government have not been accepted by the Committee :-

Sl. No. 2, 4, 6 (Total = 3)

This may be included in Chapter IV of the Draft Report.

(iv) Observations / Recommendations in respect of which final replies of the Government are still awaited:-

Sl. Nos. Nil (Total =Nil)

This may be included in Chapter V of the Draft Report.

3. The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in Chapter-I and V of this Report should be furnished expeditiously.

4. The Committee will now deal with action taken by the Government on all the Observations/Recommendations which still require reiteration or merit comments.

A. Budgetary Performance of North East Region (NER).

Recommendation (Sl. No.2)

5. While stressing that budget for the North East region be increased and equitably distributed among 8 states the Committee had recommended as under:-

"The Committee note that during the year 2017-18 at BE stage Rs. 31.52 crores was allocated for North East Region, which were increased to Rs. 38.87 crores at RE stage. As on 9.2.2018 the actual expenditure has been Rs. 31.50 crores. The BE for 2018-19 for NER has been estimated at Rs 33.52 crores and the entire provision for NER has been for NIPER Guwahati and the physical target is to complete the construction of NIPER Guwahati campus on the land allocated by the State Government as well as academic activities. Besides PMBJP Kendra's have also been assisted in NER through this fund.

The Committee note that NIPER Guwahati started its academic session in 2008 with the help of mentor institute Guwahati Medical College. Foundation stone for construction of NIPER Guwahati's own building was laid on May, 2015. 89 acres land has been allocated and Engineering Projects India Limited (EPIL) has been selected as Project Management Consultant (PMC). Construction started in June 2015, however due to fund constraints, construction has been delayed and as on date 37% construction has been done in past two and half years.

Since the entire allocation of NER is utilized for NIPER Guwahati that means from 2015-16 to 2017-18 a total of Rs. 78.77 crores has been spent on this and in only one-third of construction of NIPER Guwahati building has been completed. The Committee note that NER comprises of eight underdeveloped States Arunachal Pradesh, Assam, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura having 46 million population. To address the needs of NER, the Committee recommend to increase allocation for NER so that physical targets like NIPER Guwahati building project can be completed in a fixed timeframe. Further this increased allocation would also help PMBJP Kendra's in NER to receive adequate and timely fund assistance to attain business sustainability and extend the benefits of generic drug and medical devices to the common people of North East states. The Committee are of the view that the Department must explore the feasibility of equitable distribution of allocation meant for development of NER in Pharmaceuticals sector in all the 8 states instead of concentrating in one state for the inclusive development of this region."

Reply of the Government

6. In reply to the afore-mentioned recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"The recommendation of the Committee has been noted for compliance. Allocation under Major Head 2552(North Eastern Region) is made as per the instruction of Ministry of Finance. Out of a total budget of Rs. 261.53 Crore , 13 % was earmarked for NER amounting to Rs. 33.52 Crore. However, an amount of Rs. 46.00 crore have been released for construction/purchase of equipment during financial year 2017-18 to NIPER Guwahati. It has spent Rs. 26.85 Crore on construction activities by 31st May 2018. Nearly 47% of construction has been completed. A meeting of Expenditure Finance Committee (EFC) was held on 26th March 2018 under the Chairmanship of Finance Secretary and equipping ten NIPERs. The minutes of the meeting has been submitted for approval of Hon'ble Minister (C&F). It is expected that construction activity of NIPER Guwahati will be completed during FY 2018-19 and NIPER Guwahati will start academic session 2019-20 from its own campus.

As regards to PMBJP during 2017-18, the Government released Rs. 47.64 core to BPPI for implementing the scheme throughout the country including 'North Eastern States'. The increased allocation in the MH 2552 for North Eastern Area is no doubt, the additional financial assistance for NE States which will help functional PMBJP Kendra's in NE States to attain business sustainability by fulfilling the main objective of the scheme i.e to make available quality generic medicines at affordable price to all.

As on 31.3.2018, 3322 PMBJP Kendras were functional in 33 States/UTs of the country out of which 158 were functional in North Eastern States. A state-wise list of 158 functional PMBJP in NE states, is as under:

Sl. No.	North Eastern States	Number of PMBJP Kendras
1	Arunachal Pradesh	24
2	Assam	52
3	Manipur	36
4	Meghalaya	1
5	Mizoram	8
6	Nagaland	11
7	Sikkim	2
7	Tripura	24
	Total	**158**

As on 28.05.2018, 3600 PMBJP Kendras are functional in 34 States/UTs of the country out of which 165 PMBJP Kendras are functional in North Eastern States. A State-wise list of 165 PMBJP Kendras in NE States, is as under:

Sl. No.	North Eastern States	Number of PMBJP Kendras
1	Arunachal Pradesh	24
2	Assam	59
3	Manipur	35
4	Meghalaya	1
5	Mizoram	9
6	Nagaland	13
7	Sikkim	2
7	Tripura	22
	Total	**165**

Comments of the Committee

7. **The Committee noted that the entire allocation of NER from 2015-16 to 2017-18 was Rs. 78.77 crores which was utilized only for NIPER Guwahati and worse the more that only forty seven percent of construction of NIPER Guwahati building has been completed. The Committee recommended that there is urgent need and there is need to increase allocation for NER so that physical targets like NIPER Guwahati building project can be completed in a fixed timeframe. The increased allocation would also help PMBJP Kendra's in NER to receive adequate and timely fund assistance to attain business sustainability and extend the benefits of generic drug and medical devices to**

the common people of North East states. The Committee desired that the Department must explore the feasibility of equitable distribution of allocation meant for development of NER in Pharmaceuticals sector in all the 8 states instead of concentrating in one state for the inclusive development of this region.

The Department in their Action Taken Reply has stated that construction activity of NIPER Guwahati will be completed during FY 2018-19 and NIPER Guwahati will start academic session 2019-20 from its own campus. As regards to PMBJP during 2017-18, the Government released Rs. 47.64 core to BPPI for implementing the scheme throughout the country including 'North Eastern States'. As on 28.05.2018, 3600 PMBJP Kendras are functional in 34 States/UTs of the country out of which 165 PMBJP Kendras are functional in North Eastern States. The Committee are distressed to note that in the States of Sikkim and Meghalaya, there are only 2 and 1 PMBJP Kendras respectively. The Committee are of the view that in the States of Sikkim and Meghalaya where tough terrain exist and it becomes very difficult for the rural folk to travel far, it is imperative that more number of PMBJP Kendras be opened and made functional in the States.

The Committee, therefore reiterate their earlier recommendation that there is need to further enhance the funds for North East region so that the PMBJP kendras can be further expanded to cover each district of all 8 States of North East.

B. National Pharmaceuticals Pricing Authority (NPPA).

Recommendations No. 3

8. While stressing on optimal utilization of funds by NPPA and its Consumer Awareness Schemes, Committee had recommended as under:-

"The Committee note that during 2017-18 National Pharmaceuticals Pricing Authority (NPPA) were allocated Rs. 15 crores at BE stage which slightly got reduced to Rs 14.42 crores at RE stage and actual expenditure as on 9.2.2018 has been assessed at Rs.8.09 crores. In 2018-19 Rs. 11.50 crores have been allocated for NPPA. The Committee also note that NPPA has convened National Conference on 'Affordable Medicines' in 2016, prepared a tele-film on 'Affordability of Medicines' through DAVP, taken e-initiatives like Pharma Jan Samadhan for grievance redressal, Integrated Pharmaceutical Database Management System (IPDMS) for online submission of information by pharmaceutical manufacturers , Mobile Application 'Pharma SahiDaam' and 'Search Medicine Price' utility to facilitate easy search of the brand name, composition, ceiling price and MRP of the formulation.

The Committee note that NPPA has under-utilized its allocated funds in 2017-18 which might have impacted the outreach of its e-initiatives and other important functions. The Committee therefore recommend the Department to check underutilization of allocated funds with NPPA which though is an autonomous body and take sincere steps to optimally utilize the allocated funds. The Committee further recommend NPPA to monitor the availability and shortage of medicines in PMBJP Kendra's set up in all States/UTs.

The Committee also strongly urge upon NPPA to conduct regional conference in close coordination with Panchayati Raj and Urban Local Bodies and to arrange the tele-film on 'Affordability of Medicines' in every PanchayatGhar of the country so that people at grass root level are given firsthand information and knowledge about this. The Committee further would like the NPPA to include in their awareness campaign focus against use of spurious and expired medicines in under-developed States of the country."

9. In reply to the afore-mentioned recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"National Pharmaceutical Pricing Authority (NPPA) is an attached office of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The details of BE, RE and actual expenditure of NPPA during FY 2017-18 are given below:

Establishment Expenditure

(Rs In lakh)

Sl. No.	Particulars	BE 2017-18	RE 2017-18	Expenditure upto 31.03.18	BE 2018-19
1.	Establishment Expenditure	1100.00	1042.00	953.71	1150.00

Scheme of Consumer Awareness, Publicity and Price Monitoring

(**Rs In lakh)**

Sl. No.	**Object Head**	**BE 2017-18**	**RE 2017-18**	**Expenditure upto 31.03.18**
1.	Office Expenses	400.00	200.00	6.43
	Total	**400.00**	**200.00**	**6.43**

The scheme of Consumer Awareness, Publicity and Price Monitoring was not approved during 2017-18 and hence funds earmarked under the scheme remained unutilized.

As per detailed Demands for Grants 2018-19, total allocation under various heads is as under:

(Rs. In crore)

Sl. No	**Scheme Name**	**BE 2018-19**
1	Establishment Expenses	11.50
2	Consumer Awareness Publicity and Price Monitoring (CAPPM)	
a	Assistance to Project Monitoring Resource Units (PMRUs) – Grants in Aid General	2.00
b	Advertising and Publicity for CAPPM	2.00
	Total	**15.50**

As far as the monitoring of availability and shortage of medicines in PMBJP Kendra is concerned, it may be mentioned that PMBJP is being implemented by BPPI.

In respect of conducting regional conferences and awareness campaigns, the recommendations of the committee have been noted for compliance. In BE 2018-19 specific budgetary allocation have been made for PMRU and Advertising and Publicity for CAPPM."

Comments of the Committee

10. The Committee noted that during 2017-18 National Pharmaceuticals Pricing Authority (NPPA) were allocated Rs.15 crores at BE stage which slightly got reduced to Rs.14.42 crores at RE stage and actual expenditure as on 9.2.2018 has been assessed at Rs.8.09 crores. Hence the Committee noted that the NPPA has under-utilized its allocated funds in 2017-18 and recommended that the Department to check underutilization of allocated funds with NPPA and take steps to optimally utilize the allocated funds. The Department in their reply have stated that the scheme of Consumer Awareness, Publicity and Price Monitoring was not approved during 2017-18 and hence funds earmarked under the scheme remained unutilized. As per detailed Demands for Grants 2018-19, total allocation under Establishment expenditure is Rs. 11.50 crores and Consumer Awareness Publicity and Price Monitoring (CAPPM) is Rs 4 crores which is divided into Rs.2 crores for Assistance to Project Monitoring Resource Units (PMRUs) – Grants in Aid General and Rs.2 crores for Advertising and Publicity for Consumer Awareness, Publicity and Price Monitoring (CAPPM).

In view of the above the Committee feel that approval of schemes should have been the precondition for the allocation of funds so that funds are not

allowed to be lying unproductive and dormant and could be utilized for other urgent developmental purposes. Thus the Committee hope that the Department would take sufficient steps for optimal utilization of funds allocated and prevent any underutilization only for want of approval of schemes.

The Committee also note that the NPPA is mandated to fix/revise the prices of controlled bulk drugs and formulations and enforce prices and availability of the medicines in the country. The Department in their reply stated that monitoring of availability and shortage of medicines in PMBJP Kendra is function of BPPI (Bureau of Pharmaceutical PSUs of India). However, the Committee are not convinced with this reply as NPPA is overall regulator to ensure availability of medicine in country in general which also cover PMBJP. The Committee, therefore, reiterate its earlier recommendation that NPPA to monitor the availability of medicines at PMBJP Kendras in all States/UTs in close coordination with BPPI and Department of Pharmaceuticals to ensure that there is no dearth of medicines in PMBJP Kendras.

The Committee also hope that specific budgetary allocation for PMRU and advertising and publicity of CAPPM would augment awareness campaigns and more regional conferences would be held. The Committee would like to be informed in this regard.

C. Consumer Awareness Publicity and Price Monitoring

Recommendations (Sl. No. 4)

11. The Committee while stressing need to set up PMRU in every State and UT recommended the Department as under:-

"The Committee note that in the backdrop of the changing scenario in the pharma sector and the recommendations of various committees, the ongoing central sector scheme has been re-named as “Scheme of Consumer Awareness & Publicity and Price Monitoring” from 2015-16 onwards. As per approval of the Standing Finance Committee this scheme has 2 components, a central component and a state component. The central component includes the joint publicity campaign by the NPPA and Department of Consumer Affairs on a 50:50 cost sharing basis. The state component of the scheme comprises setting up of Price Monitoring and Resource Units (PMRUs). An amount of Rs. 5.45 crores was provided in BE (2016-17) which has been reduced to Rs. 2.87 crores under RE (2016-17) for the Scheme and actual expenditure was Rs 2.17 crores. Further the Committee note that during the year 2017-18 Rs. 4 crores were allocated at BE stage for modified scheme-Consumer Awareness, Publicity and Price Monitoring, which remained

unaltered at RE stage however, expenditure could not be incurred due to issues related to opening of a separate Head for the Plan Scheme of Consumer Awareness, Publicity and Price Monitoring with certain sub-heads, and obtaining 15 digit numeric head for the Scheme.

Now in 2018-19 again Rs.4 crores has been allocated. The Committee note that the objectives of setting up the PMRUs are to provide necessary technical assistance to the State Drug Controllers and NPPA towards monitoring the notified prices of medicines, detection of violation of the provisions of DPCO, pricing compliance and ensuring availability of medicines, monitoring the price movement of scheduled and non-scheduled formulations, collection and compilation of market based data of scheduled and non-scheduled formulations, collection of test samples of medicines from the retail market whenever required and conduct of training, seminars and workshops at the State and District levels for consumer awareness and publicity.

The Committee further note that this scheme was modified to cater to the requirement of payment for setting up of Price Monitoring and Resource Units (PMRU). The Modified scheme under approval envisaged creation of PMRUs in seven States viz Maharashtra, Gujarat, Orissa, Haryana, Kerala, Assam and Manipur on pilot basis. However, subsequently, this was limited to four States *viz*. Kerela , Gujarat, Odisha and Maharashtra and as such no time limit has been fixed. Under the revised scheme, PMRU is proposed to be a registered society under the Chairmanship of the State Drugs Controllers with representatives from NPPA, Health Department of the State Government and of Civil Societies. DO letters were sent by Chairman NPPA to Secretary (Health) of Kerala, Gujarat and Odisha for creation of societies enabling NPPA to release funds to these states after the approval of the modified scheme from Department of Pharmaceuticals. The creation of the Society as proposed in the Scheme in the respective states would enable early release of funds by NPPA.

The Committee would like the Department to convince each State and UT to have PMRU so that they can extend all necessary support to the State Drug Controllers in carrying out monitoring and enforcement activities under the Drug Price Control Order, 2013 in their respective jurisdictions, which as on date is not up to the mark. As a result of this Indian drug market is adulterated with spurious and expired drugs. PMRUs once established will also ensure that the benefits of the DPCO trickle down to the grassroots level, which is the need of the hour. Thus, the Committee recommend the Department to work in close coordination with NPPA, State Drugs Controllers, State Health Department and likeminded Civil society representatives where PMRUs are being implemented on pilot basis. Thereafter, based on the success of these pilot projects the scheme should be implemented in other states/UT within a fixed timeframe."

Reply to the Government

12. In reply to the afore-mentioned recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"During the year 2017-18, out of the RE of Rs. 2.00 crore, an amount of Rs. 6.43 lakhs was released under central component. No amount could be incurred for setting up of Price Monitoring and Resource Units (PMRU), as there was no separate Head for the Scheme of Consumer Awareness, Publicity and Price Monitoring.

For the year 2018-19, Rs. 4.00 crore has been allocated for the scheme. Government has since approved the modified scheme 'Consumer Awareness, Publicity and Price Monitoring' on 17.04.2018. The scheme will be implemented at Central level by NPPA and at the State level by registered societies of Price Monitoring & Resource Units (PMRUs).

Budget head for the scheme has also been opened. The modification in the scheme has been done to cater to the requirement of payment for setting up of Price Monitoring and Resource Units (PMRU). Under the revised scheme, PMRUs is proposed to be a registered society under the Chairmanship of the State Drugs Controllers. NPPA has requested the State Governments of Kerala, Gujarat and Odisha for creation of societies. The creation of the society as proposed in the scheme in the respective States would enable early release of funds by NPPA in order to achieve the objectives of the scheme.

The committee's recommendations in respect of working of DoP in close coordination with NPPA and other stakeholders has been noted for compliance."

Comments of the Committee

13. **The Committee have noted that Price Monitoring and Resource Units (PMRUs) are to be set up in all States and UTs under the state component of the Scheme of Consumer Awareness, Publicity and Price Monitoring. The Department during examination of Demand for Grants informed that Rs. 4 crores were allocated at BE stage during the year 2017-18 for modified scheme-Consumer Awareness, Publicity and Price Monitoring, which remained unaltered at RE stage. However, the action taken replies of the Department state that during the year 2017-18, out of the RE of Rs. 2.00 crore, an amount of Rs. 6.43 lakhs was released under Central component. Further, the Committee are distressed to know that this allocated amount could not be incurred due to issues related to opening of a separate Head for the Plan Scheme of Consumer Awareness, Publicity and Price Monitoring with certain sub-heads. The Committee areof the view that the Department has failed in utilizing the allocated amount due to lack of prior**

planning and budgetary mechanism to utilize the allocated amount for the welfare of consumers. The amount was kept dormant for whole year 2017-18, which could have been utilized optimally otherwise. Hence, the Committee strongly feel that the Department could have done adequate home work first and created proper budgetary mechanism like budget Heads so that the fund could have been utilized without any delay. The Committee note that the Budget Head has now been opened and expect that the Department will take adequate steps to expeditiously coordinate with State and UT Governments for creation of PMRUs. The Committee would like to be apprised of the action taken in this regard.

D. National Institute of Pharmaceutical Education and Research (NIPER)

Recommendations (Sl. No. 5)

14. While expressing the view that, prompt steps may be taken to give required financial handholding to NIPERs and make them the "IITs of the Pharmaceuticals sector", the Committee had recommended as under:-

"The Committee note that in order to acquire leadership position in drug discovery and development and to continue to excel in the formulations, Government recognized that human resources/talent pool is very critical. National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar (Mohali) was set up as a registered society in 1991 under the Societies Registration Act 1860, Subsequently the Institute was given statutory recognition by an act of Parliament, NIPER Act, 1998 and was declared as an Institute of National Importance. Further during 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institutes. Subsequently, NIPER at Madurai was approved in the year 2012. During 2015-16, Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh, Maharashtra and Rajasthan at New Raipur, Nagpur and Jhalawar respectively.

The Committee note that during the year 2017-18 Rs 96.23 crores were allocated to NIPER at BE stage which increased to Rs 112.81 crores at RE stage. However only Rs 88.21 was the actual expenditure. Rs 101.50 crores has been allocated for the year 2018-19 against the proposed demand of Rs 300 crores of the Department. Further, Expenditure Finance Committee proposal for 10 NIPERs has been sent to Ministry of Finance for seeking Rs. 2048.6 crores for next three years (including Rs. 1262.45 crores for 2018-19).The Committee note that on one hand department is proposing higher amount under this scheme and on the other

hand unable to utilize the allocated amount despite of pending construction work and need of new technical instruments in these institutes.

The Committee further note that all the existing NIPERs except NIPER Mohali, are presently governed by a Steering Committee under the chairmanship of Secretary, Department of Pharmaceuticals. NIPER Mohali has its own Board of Governors. All NIPERs, except NIPER Hyderabad and NIPER, Hajipur have regular Directors and process for their appointment is at final stages. Since all NIPERs except NIPER Mohali are functioning in absence of Board of Governors so the Committee recommend that all NIPERs shall be governed by their own Board of Governors. They also recommend to expedite appointment of regular Directors for NIPER Hyderabad and Hajipur for effective governance and management of these institutes.

The Committee note that department has not been able to elevate NIPERs as institutes of excellence. All NIPER institutes except Mohali are reeling under multiple problems- fund crunch, insufficient internal resource generation, pending building construction, under paid adhoc and contractual faculty, and running courses in rented buildings without requisite infrastructure support. All this has lowered the prestige and defeated the purpose for which these institutes were set up. Thus, the Committee strongly recommend that all NIPERs shall be accorded with statutory status by an act of Parliament at par with NIPER Mohali. The Committee also recommend the Department to take prompt steps to give required financial handholding to NIPERs so that pending campus construction of all NIPERS is completed in a time bound manner and good salary packages can be offered to attract best faculty in these institutes. The Committee also endorse the NITI Aayog recommendation that there is need to re-engineer business model of the NIPERs in order to make them the "IITs of the Pharmaceuticals sector" and thus department shall choke out a suitable roadmap for smooth functioning of all existing NIPERs as they have to play a pivotal role in developing highly skilled human resource for expanding Indian Pharmaceuticals sector."

Reply to the Government

15. In reply to the afore-mentioned recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"Rs. 46.00 crore have been released to NIPER Guwahati for construction/purchase of equipment during financial year 2017-18. NIPER Guwahati has spent Rs. 26.85 crore on construction activities by 31st May 218. Nearly 47% of construction has been completed. A meeting of Expenditure Finance Committee (EFC) was held on 26th March 218 under the Chairmanship of Finance Secretary and equipping ten NIPERs. The minutes of the meeting has

been submitted for approval of Hon'ble Minister (C&F). It is expected that construction activity of NIPER Guwahati will be completed during FY 2018-19 and NIPER Guwahati will start academic session 2019-20 from its own campus.

Once sufficient funds are allocated by Ministry of Finance, construction activities in NIPERs will be started and they will be equipped with basic infrastructure like lab, equipments. Action will be initiated to create sanctioned posts from Department of Expenditure.

Director, NIPER Hyderabad has been selected and file is under submission for approval of Visitor. Applications for selection of Director NIPER Hajipur have been received. The re-constituted Search cum Selection Committee has been requested to expedite the selection process of Director Hajipur. It is expected that both posts will be filled up shortly. Action has been taken to constitute the Board of Governors (BoG) for six NIPERs."

Comments of the Committee

16. The Committee had noted in their original Report that the Department of Pharmaceuticals has not been able to elevate NIPERs as institutes of excellence. All NIPER institutes except Mohali are reeling under multiple problems- fund crunch, insufficient internal resource generation, pending building construction, under paid adhoc and contractual faculty, and running courses in rented buildings without requisite infrastructure support.

The Committee note that the Department in their Action Taken Reply have stated that NIPER Guwahati will be completed during FY 2018-19 and NIPER Guwahati will start academic session 2019-20 from its own campus. The Department has assured that once sufficient funds are allocated by Ministry of Finance, construction activities in NIPERs will be started and they will be equipped with basic infrastructure like lab, equipments and action will be initiated to create sanctioned posts from Department of Expenditure. The re-constituted Search cum Selection Committee has been requested to expedite the selection process of Director Hajipur. It is expected that both posts will be filled up shortly.

The Committee appreciate the Department for having taken due note of all matters raised by this Committee on functioning of NIPERs. However , they are still not fully satisfied and convinced with the stereotyped reply of the Department that paucity of funds is stumbling block in the construction of NIPERs. The Department/Ministry should have taken the matter with Ministry of Finance at the highest level and obtain requisite fund for developing all NIPERs. The Committee are of the strong view that piece meal measure are not going to empower the existing NIPERs as institutes of

excellence unless they are supported closely. They, therefore, cannot help but reiterate their earlier recommendation and would like to be apprised of the action taken in this regard.

E. National centre For R&D in Bulk Drug

Recommendations Sl. No. 6

17. While expressing that the Department to swiftly utilize the funds allocated for Bulk Drug Industry, the Committee had recommended as under:-

"The Committee note that the Department initiated setting up of National Centre for R&D in Bulk Drug (NCRDBD), in order to promote inter-linkages with the industry at the allocated site of NIPER-Hyderabad at Genome Valley of Medak District. Standing Finance Committee (SFC) has approved Rs.54.20 crores in 2014 for this purpose. However, Rs. 12 crores was actual utilization under this scheme in 2015-16. During the year 2016-17 and 2017-18 only Rs 0.01 crores has been allocated but there is nil actual utilization in both the years. In the year 2018-19 as well no allocation has been done under this scheme. The Committee note that the first and foremost challenge is availability of cheaper imported Active Pharmaceutical Ingredients (APIs) after globalization, which has badly hit the indigenous bulk drug development & industry. The Committee further note that the bulk drug industry is highly polluting and its effluents are highly hazardous, whose treatment adds to the cost of production. For this the government has started a scheme for assistance to Bulk Drug Parks in which Govt. will fund the common facility including Effluent Treatment Plants. The Standing Finance Committee (SFC) has Further approved Assistance to Bulk Drug Industry for Common Facilitation Centre on 7.2.2018. The Committee recommend the Department to swiftly utilize the allocated funds under this scheme for Bulk Drug industry. The Committee also note that inverted duty structure is also adversely impacting the bulk drug production sector and recommend the Department to address the major issue of inverted duty structure so that import of bulk drugs can be checked and domestic bulk drug industry is made competitive and sustainable."

Reply of the Government

18. In reply to the afore-mentioned recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"An Memorandum of Understanding (MoU) was signed between National Projects Construction Corporation Ltd (NPCC) and NIPER Hyderabad for Setting

up National Centre for R&D in Bulk Drug (NCRDBD) with project outlays for Rs. 54.20 crore after approval of Standing Finance Committee (SFC). Accordingly, Rs.12.00 crore were released during FY 2015-16. Since the construction of NIPER Hyderabad campus has been delayed due to scarcity of funds, the activity for establishment of NCRDBD could not be initiated. NIPER Hyderabad has been requested to return unutilized funds to Government.

Department of Pharmaceuticals had recommended to Ministry of Finance correction of Inverted Duty Structure in Pharmaceuticals Industry. Ministry of Finance vide notification No. 6/2016-Customs dated 28.1.2016 withdrew the Custom Duty exemptions granted to certain categories of drugs/bulk drugs."

Comments of the Committee

19. The Committee observed that the Department has initiated setting up of National Centre for R&D in Bulk Drug (NCRDBD), in order to promote inter-linkages with the industry at the allocated site of NIPER-Hyderabad. In their Action Taken Reply the Department stated that an Memorandum of Understanding (MoU) was signed between National Projects Construction Corporation Ltd (NPCC) and NIPER Hyderabad for Setting up National Centre for R&D in Bulk Drug (NCRDBD) with project outlays for Rs. 54.20 crore after approval of Standing Finance Committee (SFC). Accordingly, Rs.12.00 crore were released during FY 2015-16. Since the construction of NIPER Hyderabad campus has been delayed due to scarcity of funds, the activity for establishment of NCRDBD could not be initiated. NIPER Hyderabad has been requested to return unutilized funds to Government.

The Committee seriously find that there is clear cut contradiction in version of the action taken reply of the Government wherein the latter has stated on one hand that the construction work for NIPER, Hyderabad got delayed due to scarcity of funds and on the other hand NIPER Hyderabad is directed to return unutilized funds. The Committee, therefore, reiterate that the Department of Pharmaceuticals to take setting up of National Centre for R&D in Bulk Drug (NCRDBD) on priority basis alongwith hazardous effluents treatment plant. The Committee, would like to be apprised of the action taken by the Department in this regard.

F. Development of Pharmaceuticals Industry

Recommendations (Sl. No. 7)

20. The Committee while stressing on optimal utilization of funds under umbrella Scheme for Development of Pharma Industry Recommended as under:-

" The Committee note that 'Scheme for Development of Pharma industry' is an Umbrella Scheme comprising of five sub-schemes (i)Assistance to Bulk Drug Industry for Common Facilitation Centres, (ii) Assistance to Medical Device Industry for Common Facilitation Centres, (iii) Assistance to Pharmaceutical Industry (CDP-PS) (iv) Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS) and (v) Pharmaceutical Promotion and Development Scheme (PPDS). During 2017-18 Rs 17.02 crores were allocated at BE stage which reduced to Rs 12.03 crores at RE stage and actual expenditure was just Rs. 0.77 crores. Now for the current year 2018-19 Rs 12.97 crores have been allocated. The committee note that department has not utilized the allocation made under three ongoing sub-schemes mentioned above at (iii), (iv) and (v) . Two sub-scheme mentioned above at (i) and (ii) are a fresh initiative of the Department and was considered by the SFC in its meeting held on 7/2/2018 only.

The Committee also note that the Department Action Plan for 2018-19 under 'Scheme for Development of Pharma industry' with budget allocation of Rs 12.97 crores are- (i) Initiation of Common Facility Centres in 2 Bulk Drug Parks under sub scheme Assistance to Bulk Drug Parks for Common Facility Centre which needs up to Rs.100 Crores, (ii) Initiation of Common Facility Centres in 2 Medical Device Parks under sub-scheme Assistance to Medical Device Parks for Common Facility Centre which needs up to Rs.25 Crores, (iii) Up-gradation to WHO-GMP standards of up to 100 units in private sector under sub-scheme Pharmaceuticals Technology Up-gradation Assistance Scheme(PTUAS), (iv) Initiation of Common Facilities Centres in 3 Clusters promoted by Special Purpose Vehicle (SPV) under sub-scheme Cluster Development Programme for Pharma Sector (CDP-PS) and (v) Conducting India Pharma and Indian Medical Expo; seminars, exhibitions etc. under Pharmaceutical Promotion & Development Scheme (PPDS).The Committee further note that the Cluster Development Programme for Pharma Sector (CDP-PS) scheme could not take off despite the best efforts of the Government and Projects and Development India Limited (PDIL), the Project Management Consultant (PMC) had called for four expression of Interest (EOIs) and the responses were not encouraging in spite of the modification in the scheme and only one Special Purpose Vehicle (SPV) has been found suitable.

The Committee seriously note the gross underutilization of funds during 2017-18 which has impacted the implementation process of these sub-schemes. The Committee further note that the Department has clubbed these schemes under an umbrella programme which gives flexibility to utilize funds in these sub-schemes as and when needed. The Committee are of considered view that unless and until the problem of underutilization is duly addressed, no effective outcomes intended by these sub-schemes will be achieved. Thus the Committee recommend

the Department to take necessary steps to ensure optimum utilization of allocated funds under this Scheme for Development of Pharmaceuticals industry and enhance the allocation at RE stage as the current allocation of Rs12.97 crores at BE stage is grossly insufficient for accomplishing the aforesaid Action Plan of the Department for the year 2018-19. The Committee further recommend the Department to take innovative steps to generate pharmaceutical industry attraction towards Cluster development programme so as to disseminate benefit of economies of scale and increase production of affordable medicines in the country at large scale."

Reply of the Government

21. In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"It is brought to the notice of the committee that of the five sub-schemes comprising the Scheme for Development of Pharmaceuticals Industry, only two sub schemes viz. CDP-PS & PPDS are ongoing scheme and the other three sub-schemes are fresh initiatives which were considered by the SFC in the meeting held on 07.02.2018. The draft guidelines for implementing the scheme have now been approved. All efforts will be made to ensure optimum utilization of allocated funds in accordance with the approved guidelines.

The recommendation of the Committee to enhance the allocation at RE stage has been noted and would be taken up at the appropriate time keeping in view the funds requirement at the time. The Committee's recommendation to take innovative steps to generate Pharmaceuticals Industry attraction towards Cluster Development Programme has been noted for further compliance."

Comments of the Committee

22. **The Committee had noted that Department allocated Rs 12.97 crores for the Action Plan for 2018-19 under 'Scheme for Development of Pharma industry' which includes (i) Initiation of Common Facility Centres in 2 Bulk Drug Parks under sub scheme Assistance to Bulk Drug Parks for Common Facility Centre which needs up to Rs.100 Crores, (ii) Initiation of Common Facility Centres in 2 Medical Device Parks under sub-scheme Assistance to Medical Device Parks for Common Facility Centre which needs up to Rs.25 Crores, (iii) Up-gradation to WHO-GMP standards of up to 100 units in private sector under sub-scheme Pharmaceuticals Technology Up-gradation Assistance Scheme(PTUAS), (iv) Initiation of Common Facilities Centres in 3 Clusters promoted by Special Purpose Vehicle (SPV) under sub-scheme**

Cluster Development Programme for Pharma Sector (CDP-PS) and (v) Conducting India Pharma and Indian Medical Expo; seminars, exhibitions etc. under Pharmaceutical Promotion & Development Scheme (PPDS). However during 2017-18 Rs 17.02 crores were allocated at BE stage which reduced to Rs 12.03 crores at RE stage but actual expenditure was just Rs. 0.77 crores.

The Department in their action taken reply has simply assured compliance of the Committee's recommendation on optimal utilization of allocated funds, enhance the allocation at RE stage and innovative steps to take off Cluster Development Programme. However, no concrete action plan to translate the assurance given into reality has been dwelt upon. The Committee are not satisfied with the stereotyped reply of the Department and therefore, reiterate their earlier recommendation to chalk out a concrete action plan for the smooth implementation of the umbrella Scheme for Development of Pharma Industry and would like to be apprised of the action taken in this regard.

CHAPTER – II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendations (Sl. No. 1)

The Committee note that during the year 2017-18 Rs 247.74 crores was allocated to Department of Pharmaceuticals at BE stage, which got increased to Rs 266.09 crores at RE stage but as on 9.02.2018 the actual expenditure of the Department of Pharmaceuticals has been only Rs 190.17crores which is Rs 75.92 crores short of the allocated budget. This reflects on poor budgetary planning and dissatisfactory fund utilization capacity of the Department of Pharmaceuticals, which would also result in lowering the pace of implementation of all crucial schemes viz. NIPERs, Jan Aushadhi (PMBJP) scheme for Development of Pharma Industry and assistance to PSUs. This also further contradicts the fund constraint argument given by the Department while explaining their inability to fulfill their physical targets under various schemes pending for want of sufficient funds.

The Committee also notes that time and again the Department is resorting to supplementary grants from Ministry of Finance which has added an additional channel of approval with regard to funds allocation and disbursement apart from annual allocation. The Committee consider that this could have been avoided had the Department undertaken in-depth assessment of its budgetary requirements and thereafter had also utilized the allocated funds in a time bound manner. However, poor budgetary planning and delays in utilization of funds has not only affected Department's Budgetary performance but has also impacted its noble mandate of providing affordable drugs and medicals devices to the poor people of the country. The Committee further note that relatively shorter financial lending terms for long gestation research and development projects of pharmaceuticals and need for incentivizing innovation activities are major obstacles to the growth of pharmaceuticals sector in the country.

The Committee therefore, strongly recommend the Department to stress upon scientific budgetary planning, effectively utilize allocated funds in time bound manner, enhance efficiency of its internal budgetary analysis, address structural and procedural lacunas coming in way of fund utilization and take up the issue of long term financial lending facility for long gestation pharmaceuticals projects and providing more tax incentives for such projects with the Ministry of Finance.

Reply of the Government

Details of original allocation under Budget Estimates, Revised Estimates and Actual expenditure during the last six financial years are given below:

(Rs. In crore)

Scheme	BE	RE	Actual Expenditure	% actual vs RE	Supplementary
2015-16	259.02	219.39	212.66	96.93	24.29
2016-17	211.40	211.40	*307.57	145.49	100.02
2017-18	247.74	266.11	252.41	94.85	18.37

*Supplementary Rs.100.00 crores loan to HAL for Salary etc.

It can be seen that during the last 3 financial years the Department has been consistently able to utilize 95 % of the funds allocated to it at the RE stage by the Ministry of Finance. Suggestions of the Committee have been noted for compliance for better utilization of funds in future.

Recommendations (Sl. No. 3)

The Committee note that during 2017-18 National Pharmaceuticals Pricing Authority (NPPA) were allocated Rs. 15 crores at BE stage which slightly got reduced to Rs 14.42 crores at RE stage and actual expenditure as on 9.2.2018 has been assessed at Rs.8.09 crores. In 2018-19 Rs. 11.50 crores have been allocated for NPPA. The Committee also note that NPPA has convened National Conference on 'Affordable Medicines' in 2016, prepared a tele-film on 'Affordability of Medicines' through DAVP, taken e-initiatives like Pharma Jan Samadhan for grievance redressal, Integrated Pharmaceutical Database Management System (IPDMS) for online submission of information by pharmaceutical manufacturers , Mobile Application 'Pharma Sahi Daam' and 'Search Medicine Price' utility to facilitate easy search of the brand name, composition, ceiling price and MRP of the formulation.

The Committee note that NPPA has under-utilized its allocated funds in 2017-18 which might have impacted the outreach of its e-initiatives and other important functions. The Committee therefore recommend the Department to check underutilization of allocated funds with NPPA which though is an autonomous body and take sincere steps to optimally utilize the allocated funds. The Committee further recommend NPPA to monitor the availability and shortage of medicines in PMBJP Kendra's set up in all States/UTs.

The Committee also strongly urge upon NPPA to conduct regional conference in close coordination with Panchayati Raj and Urban Local Bodies and to arrange the tele-film on 'Affordability of Medicines' in every Panchayat Ghar of the country so that people at grass root level are given firsthand information and knowledge about this. The Committee further would like the NPPA to include in their awareness campaign focus against use of spurious and expired medicines in under-developed States of the country.

Reply of the Goverment

National Pharmaceutical Pricing Authority (NPPA) is an attached office of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The details of BE, RE and actual expenditure of NPPA during FY 2017-18 are given below:

Establishment Expenditure

(Rs In lakh)

Sl.No.	**Particulars**	**BE 2017-18**	**RE 2017-18**	**Expenditure upto 31.03.18**	**BE 2018-19**
1.	Establishment Expenditure	1100.00	1042.00	953.71	1150.00

Scheme of Consumer Awareness, Publicity and Price Monitoring

(**Rs In lakh)**

Sl. No.	**Object Head**	**BE 2017-18**	**RE 2017-18**	**Expenditure upto 31.03.18**
1.	Office Expenses	400.00	200.00	6.43
	Total	**400.00**	**200.00**	**6.43**

The scheme of Consumer Awareness, Publicity and Price Monitoring was not approved during 2017-18 and hence funds earmarked under the scheme remained unutilized.

As per detailed Demands for Grants 2018-19, total allocation under various heads is as under:

(Rs. In crore)

Sl. No	**Scheme Name**	**BE 2018-19**
1	Establishment Expenses	11.50
2	Consumer Awareness Publicity and Price Monitoring (CAPPM)	

a	Assistance to Project Monitoring Resource UnitS (PMRUs) – Grants in Aid General	2.00
b	Advertising and Publicity for CAPPM	2.00
	Total	**15.50**

As far as the monitoring of availability and shortage of medicines in PMBJP Kendra is concerned, it may be mentioned that PMBJP is being implemented by BPPI.

In respect of conducting regional conferences and awareness campaigns, the recommendations of the committee have been noted for compliance. In BE 2018-19 specific budgetary allocation have been made for PMRU and Advertising and Publicity for CAPPM.

Comments of the Committee

(Please see Para No.10 of Chapter- I of the Report)

Recommendations (Sl. No. 5)

The Committee note that in order to acquire leadership position in drug discovery and development and to continue to excel in the formulations, Government recognized that human resources/talent pool is very critical. National Institute of Pharmaceutical Education & Research (NIPER) at SAS Nagar (Mohali) was set up as a registered society in 1991 under the Societies Registration Act 1860, Subsequently the Institute was given statutory recognition by an act of Parliament, NIPER Act, 1998 and was declared as an Institute of National Importance. Further during 2007-08, six new NIPERs were started at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli with the help of Mentor Institutes. Subsequently, NIPER at Madurai was approved in the year 2012. During 2015-16, Finance Minister in his Budget Speech announced 3 new NIPERs for the states of Chhattisgarh, Maharashtra and Rajasthan at New Raipur, Nagpur and Jhalawar respectively.

The Committee note that during the year 2017-18 Rs 96.23 crores were allocated to NIPER at BE stage which increased to Rs 112.81 crores at RE stage. However only Rs 88.21 was the actual expenditure. Rs 101.50 crores has been allocated for the year 2018-19 against the proposed demand of Rs 300 crores of the Department. Further, Expenditure Finance Committee proposal for 10 NIPERs has been sent to Ministry of Finance for seeking Rs. 2048.6 crores for next three years (including Rs. 1262.45 crores for 2018-19).The Committee note that on one hand department is proposing higher amount under this scheme and on the other

hand unable to utilize the allocated amount despite of pending construction work and need of new technical instruments in these institutes.

The Committee further note that all the existing NIPERs except NIPER Mohali, are presently governed by a Steering Committee under the chairmanship of Secretary, Department of Pharmaceuticals. NIPER Mohali has its own Board of Governors. All NIPERs, except NIPER Hyderabad and NIPER, Hajipur have regular Directors and process for their appointment is at final stages. Since all NIPERs except NIPER Mohali are functioning in absence of Board of Governors so the Committee recommend that all NIPERs shall be governed by their own Board of Governors. They also recommend to expedite appointment of regular Directors for NIPER Hyderabad and Hajipur for effective governance and management of these institutes.

The Committee note that department has not been able to elevate NIPERs as institutes of excellence. All NIPER institutes except Mohali are reeling under multiple problems- fund crunch, insufficient internal resource generation, pending building construction, under paid ad-hoc and contractual faculty, and running courses in rented buildings without requisite infrastructure support. All this has lowered the prestige and defeated the purpose for which these institutes were set up. Thus, the Committee strongly recommend that all NIPERs shall be accorded with statutory status by an act of Parliament at par with NIPER Mohali. The Committee also recommend the Department to take prompt steps to give required financial handholding to NIPERs so that pending campus construction of all NIPERS is completed in a time bound manner and good salary packages can be offered to attract best faculty in these institutes. The Committee also endorse the NITI Aayog recommendation that there is need to re-engineer business model of the NIPERs in order to make them the "IITs of the Pharmaceuticals sector" and thus department shall choke out a suitable roadmap for smooth functioning of all existing NIPERs as they have to play a pivotal role in developing highly skilled human resource for expanding Indian Pharmaceuticals sector.

Reply to the Government

Rs. 46.00 crore have been released to NIPER Guwahati for construction/purchase of equipment during financial year 2017-18. NIPER Guwahati has spent Rs. 26.85 crore on construction activities by 31st May 218. Nearly 47% of construction has been completed. A meeting of Expenditure Finance Committee (EFC) was held on 26th March 218 under the Chairmanship of Finance Secretary and equipping ten NIPERs. The minutes of the meeting has been submitted for approval of Hon'ble Minister (C&F). It is expected that construction activity of NIPER Guwahati will be completed during FY 2018-19 and NIPER Guwahati will start academic session 2019-20 from its own campus.

Once sufficient funds are allocated by Ministry of Finance, construction activities in NIPERs will be started and they will be equipped with basic infrastructure like lab, equipments. Action will be initiated to create sanctioned posts from Department of Expenditure.

Director, NIPER Hyderabad has been selected and file is under submission for approval of Visitor. Applications for selection of Director NIPER Hajipur have been received. The re-constituted Search cum Selection Committee has been requested to expedite the selection process of Director Hajipur. It is expected that both posts will be filled up shortly.

Action has been taken to constitute the Board of Governors (BoG) for six NIPERs.

Comments of the Committee

(Please see Para No.16 of Chapter- I of the Report)

Recommendations (Sl. No. 7)

The Committee note that 'Scheme for Development of Pharma industry' is an Umbrella Scheme comprising of five sub-schemes (i)Assistance to Bulk Drug Industry for Common Facilitation Centres, (ii) Assistance to Medical Device Industry for Common Facilitation Centres, (iii) Assistance to Pharmaceutical Industry (CDP-PS) (iv) Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS) and (v) Pharmaceutical Promotion and Development Scheme (PPDS). During 2017-18 Rs 17.02 crores were allocated at BE stage which reduced to Rs 12.03 crores at RE stage and actual expenditure was just Rs. 0.77 crores. Now for the current year 2018-19 Rs 12.97 crores have been allocated. The committee note that department has not utilized the allocation made under three ongoing sub-schemes mentioned above at (iii), (iv) and (v) . Two sub-scheme mentioned above at (i) and (ii) are a fresh initiative of the Department and was considered by the SFC in its meeting held on 7/2/2018 only.

The Committee also note that the Department Action Plan for 2018-19 under 'Scheme for Development of Pharma industry' with budget allocation of Rs 12.97 crores are- (i) Initiation of Common Facility Centres in 2 Bulk Drug Parks under sub scheme Assistance to Bulk Drug Parks for Common Facility Centre which needs up to Rs.100 Crores, (ii) Initiation of Common Facility Centres in 2 Medical Device Parks under sub-scheme Assistance to Medical Device Parks for Common Facility Centre which needs up to Rs.25 Crores, (iii) Up-gradation to WHO-GMP standards of up to 100 units in private sector under sub-scheme Pharmaceuticals Technology Up-gradation Assistance Scheme(PTUAS), (iv) Initiation of Common Facilities Centres in 3 Clusters promoted by Special Purpose Vehicle (SPV) under sub-scheme Cluster Development Programme for Pharma

Sector (CDP-PS) and (v) Conducting India Pharma and Indian Medical Expo; seminars, exhibitions etc. under Pharmaceutical Promotion & Development Scheme (PPDS).The Committee further note that the Cluster Development Programme for Pharma Sector (CDP-PS) scheme could not take off despite the best efforts of the Government and Projects and Development India Limited (PDIL), the Project Management Consultant (PMC) had called for four expression of Interest (EOIs) and the responses were not encouraging in spite of the modification in the scheme and only one Special Purpose Vehicle (SPV) has been found suitable.

The Committee seriously note the gross underutilization of funds during 2017-18 which has impacted the implementation process of these sub-schemes. The Committee further note that the Department has clubbed these schemes under an umbrella programme which gives flexibility to utilize funds in these sub-schemes as and when needed. The Committee are of considered view that unless and until the problem of underutilization is duly addressed, no effective outcomes intended by these sub-schemes will be achieved. Thus the Committee recommend the Department to take necessary steps to ensure optimum utilization of allocated funds under this Scheme for Development of Pharmaceuticals industry and enhance the allocation at RE stage as the current allocation of Rs12.97 crores at BE stage is grossly insufficient for accomplishing the aforesaid Action Plan of the Department for the year 2018-19. The Committee further recommend the Department to take innovative steps to generate pharmaceutical industry attraction towards Cluster development programme so as to disseminate benefit of economies of scale and increase production of affordable medicines in the country at large scale.

Reply of the Government

It is brought to the notice of the committee that of the five sub-schemes comprising the Scheme for Development of Pharmaceuticals Industry, only two sub schemes viz. CDP-PS & PPDS are ongoing scheme and the other three sub-schemes are fresh initiatives which were considered by the SFC in the meeting held on 07.02.2018. The draft guidelines for implementing the scheme have now been approved. All efforts will be made to ensure optimum utilization of allocated funds in accordance with the approved guidelines.

The recommendation of the Committee to enhance the allocation at RE stage has been noted and would be taken up at the appropriate time keeping in view the funds requirement at the time. The Committee's recommendation to take innovative steps to generate Pharmaceuticals Industry attraction towards Cluster Development Programme has been noted for further compliance.

Comments of the Committee

(Please see Para No.22 of Chapter- I of the Report)

Recommendations (Sl. No. 8)

The Committee note that Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in November, 2008 across the country. These specific outlets are now called "Pradhan Bhartiya Janaushadhi Pariyojana (PMBJP) Kendra's". The scheme is being implemented through an agency namely Bureau of Pharma PSUs of India (BPPI) (the implementing agency of PMBJP) which is working under the administrative control of Department of Pharmaceuticals, Ministry of Chemicals &Fertilizers, Government of India. During the year 2017-18, Rs. 74.62 crores have been allocated at RE stage and Rs.47.64 crores was released to BPPI but only Rs 29.63 crores have been the actual utilization under this scheme. During the current year 2018-19, the allocation at BE stage has been increased to Rs.84 crores. Further as per the three year plan of the PMBJP, 1000 more PMBJP Kendra's have been targeted to open in the country in each financial year beyond 2017-18 that is 2018-19 and 2019-2020.

The Committee appreciate that the Department has expanded the outreach of PMBJP Kendra's and as on27.02.2018, 3,195 PMBJP Kendras' are functional in 33 States / Union Territories of the country. Further for smooth supply of medicines, surgical and consumables to PMBJP Kendras through Central Ware House (CWH) of Bureau of Pharma PSUs of India (BPPI) (the implementing agency of PMBJP), 8 Carrying & Forwarding (C&F) Agents and 53 Distributors have been appointed in different parts of the country. The product basket of the scheme has also been expanded to cover more than 700 medicines and 154 surgical& consumables covering all major therapeutic groups such as Anti-infective, Anti-diabetics, Cardio vascular, Anti-cancers, Gastro-intestinal medicines, etc. However, the Committee observe that the current supply chain mechanism for 3195 functional Kendra is not sufficient to provide timely supply of generic drugs and medical devices to common people. Thus, the Committee recommend the Department to explore the feasibility for opening of Regional Warehouses and expand its Carrying & Forwarding (C&F) Agents and Distributors network on need basis in areas facing supply side limitations. They also recommend that a technology based real time tracking system from CWC to PMBJP Kendra be evolved to ensure pilferage free supply of generic medicines and medical devices.

Reply of the Government

Jan Aushadhi Scheme has been revised the renamed as 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)'.During 2017-18, Rs. 74.62 crore was allocated at BE stage for PMBJP which reduced to Rs. 54.62 crore at RE stage. During 2017-18, Rs. 47.64 crore was released to BPPI which was the actual expenditure under PMBJP. Hence, Rs. 6.98 crore remained unspent as on 31.3.2018. As on 31.3.2018, Rs. 44.51 crore was the actual utilization out of Rs. 47.64 crore released to BPPI under PMBJP and hence, Rs. 3.03 crores remained unspent.

As on 18.05.2018, 3571 PMBJP Kendra's are functional in 33 States/UTs of the country. As per the present supply chain management system of PMBJP, 1 central ware house (CWH) is established at IDPL Complex, Gurugram, Haryana. Besides this, 8 carrying and forward (C&F) Agents and 53 Distributors are also appointed in different parts of the country to ensure continuous supply of medicines, surgical and consumables to 3571 PMBJP Kendra's across the country. Besides this, an IT enabled end to end supply chain system has also been introduced through a SAP (Systems, Applications, Product in data processing) based software for making full range of medicines available at BPPI's Central Ware House (CWH) to all PMBJP Kendra's, through auto ordering and dispatching. This system has a provision for real time recording and tracking the receiving and dispatching of medicines form CWH, Gurugram at all physical locations. Under this system, a professional agency namely M/s Ethics Infinity Pvt. Ltd has been appointed by BPPI for providing end to end supply chain management solution for the scheme wherein medicines and other products will be supplied from CWH to PMBJP Kendra's directly to save time and cost. BPPI is also in process of opening regional warehouses at Kolkata, Guwahati, Mumbai, Nagpur, Indore, Chennai and Bangalore by the end of July 2018 for ensuring uninterrupted supply of medicines to PMBJP Kendra's. BPPI is also implementing 'Point of Sale' software application at all PMBJP Kendra's so that the Kendra's can order medicines on real time basis and can receive medicines directly from Central warehouse/regional warehouses. With the help of such state of art and customized IT enabled system, BPPI is looking to reduce its turnaround time for dispatching orders to PMBJP Kendra's to 24 hour and for delivering to the Kendra's to 96 hours. BPPI is committed to ensure smooth and prescribed interrupted supply of order within the minimum turnaround time.

CHAPTER – III

OBSERVATION / RECOMMENDATION WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLY

Recommendations (Sl.No. 9)

The Committee note that of the five PSUs, three viz. Indian Drug & Pharmaceuticals Limited(IDPL),Hindustan Antibiotic Limited(HAL)&Bengal Chemicals & Pharmaceuticals Limited (BCPL) are sick and referred to Board for Industrial & Financial Reconstruction(BIFR). Rajasthan Drugs & Pharmaceuticals Limited (RDPL) has reported losses since 2013-14 and is incipient sick. Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) is the only profit making CPSE. The Committee also note that from 2015-16the Department has changed its scheme from Project Based Support to PSU to new scheme Assistance to PSUs. Under Assistance to PSUs Scheme during 2015-16 Rs.0.04 crores were allocated at BE stage which was withdrawn at RE stage. During 2016-17 Rs.0.10 crores were allocated at BE and RE stage, however actual utilization was nil. During 2017-18 Rs.0.06 crores were allocated at BE and RE stage with nil actual utilization. For the current year 2018-19 again Rs.0.06 crores have been allocated.

Further the Committee note that the Cabinet meeting held on 28.12.2016 decided that only that much of surplus land of HAL, IDPL, RDPL and BCPL as would be required to meet the liabilities be sold through open competitive bidding to Government agencies and the outstanding liabilities be cleared from the sale proceeds. Voluntary Separation Scheme/ Voluntary Retirement Scheme also be implemented in these PSUs to pave way for their closure. Remaining part of the land should be managed in accordance with guidelines of Department of Investment and Public Asset Management (DIPAM) and Department of Public Enterprises (DPE) in this regard and if need be, vested in a SPV created for this purpose. After liabilities have been met, balance sheet cleansed and the Voluntary Separation Scheme/Voluntary Retirement Scheme effected, the Department to close IDPL and RDPL and HAL and BCPL be put up for strategic sale. The Committee also note that Cabinet Committee on Economic Affairs (CCEA) in its meeting held on 1.11.2017 has 'in principle' approved strategic disinvestment of 100% Government of India equity in Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Bengaluru through a two-stage auction process.

The Committee note that the allocation under Assistance to PSUs is only a token allocation, the reason is well known that is to keep the head open and alive for seeking more funds in future. However at the same time the Committee impress upon the Department to implement the decisions of the Cabinet Committee on Economic Affairs (CCEA) dated 28.12.2016 and 1.11.2017

respectively. The Committee further recommend the Department to ensure accurate evaluation of PSUs assets before going for strategic sale to private players. The Committee also recommend the Department to focuson internal administrative streamlining and management reforms in RDPL in the same way as BCPL has done in 2017-18, till a final way out is reached.

Reply of the Government

The Department is taking necessary steps for implementation of the decision of Cabinet/CCEA dated 28.12.2016 and 01.11.2017 respectively. It has been decided to close IDPL and RDPL and strategically sell BCPL and HAL after meeting their liabilities from sale of their surplus land. In pursuance of the Cabinet Decision, the Department t has obtained Non objection from the state Government concerned, wherever required for sale of land of all four PSUs. The tender for the land were issued through the authorized Auctioning agency , M/s MSTC.

In order to achieve better response to the tenders, advertisements were issued in newspapers. Further, the Central Government Departments State Government and Maharashtra PSUs and Financial institutions are requested to bid for the land.

As IDPL and HAL had huge outstanding with consortium of Banks and negotiations at their level did not yield results, the Department held joint negotiation and was able to persuade banks to take substantial 'haircuts' and finalized 'One Time Settlement. RDPL and HAL have framed voluntary retirement schemes (VRS) for their surplus employees.

As regard valuation of the assets of the companies under strategic sale, the same would be done as per the department of investment and public assets management (DIPAM) guidelines. Further, it is informed that production activities at RDPL have stopped after fire at its plant in October 2016. As the Government has already taken a decision for its closure, administrative and streamlining management reforms at its junction is not required.

CHAPTER – IV

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE AND WHICH REQUIRE REITERATION

Recommendations (Sl. No. 2)

The Committee note that during the year 2017-18 at BE stage Rs. 31.52 crores was allocated for North East Region, which were increased to Rs. 38.87 crores at RE stage. As on 9.2.2018 the actual expenditure has been Rs. 31.50 crores. The BE for 2018-19 for NER has been estimated at Rs 33.52 crores and the entire provision for NER has been for NIPER Guwahati and the physical target is to complete the construction of NIPER Guwahati campus on the land allocated by the State Government as well as academic activities. Besides PMBJP Kendra's have also been assisted in NER through this fund.

The Committee note that NIPER Guwahati started its academic session in 2008 with the help of mentor institute Guwahati Medical College. Foundation stone for construction of NIPER Guwahati's own building was laid on May, 2015. 89 acres land has been allocated and Engineering Projects India Limited (EPIL) has been selected as Project Management Consultant (PMC). Construction started in June 2015, however due to fund constraints, construction has been delayed and as on date 37% construction has been done in past two and half years.

Since the entire allocation of NER is utilized for NIPER Guwahati that means from 2015-16 to 2017-18 a total of Rs. 78.77 crores has been spent on this and in only one-third of construction of NIPER Guwahati building has been completed. The Committee note that NER comprises of eight underdeveloped States Arunachal Pradesh, Assam, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura having 46 million population. To address the needs of NER, the Committee recommend to increase allocation for NER so that physical targets like NIPER Guwahati building project can be completed in a fixed timeframe. Further this increased allocation would also help PMBJP Kendra's in NER to receive adequate and timely fund assistance to attain business sustainability and extend the benefits of generic drug and medical devices to the common people of North East states. The Committee are of the view that the Department must explore the feasibility of equitable distribution of allocation meant for development of NER in Pharmaceuticals sector in all the 8 states instead of concentrating in one state for the inclusive development of this region.

Reply of the Goverment

The recommendation of the Committee has been noted for compliance. Allocation under Major Head 2552(North Eastern Region) is made as per the instruction of Ministry of Finance. Out of a total budget of Rs. 261.53 Crore , 13 % was earmarked for NER amounting to Rs. 33.52 Crore. However, an amount of Rs. 46.00 crore have been released for construction/purchase of equipment during financial year 2017-18 to NIPER Guwahati. It has spent Rs. 26.85 crore on construction activities by 31st May 2018. Nearly 47% of construction has been completed. A meeting of Expenditure Finance Committee (EFC) was held on 26th March 2018 under the Chairmanship of Finance Secretary and equipping ten NIPERs. The minutes of the meeting has been submitted for approval of Hon'ble Minister (C&F). It is expected that construction activity of NIPER Guwahati will be completed during FY 2018-19 and NIPER Guwahati will start academic session 2019-20 from its own campus.

As regards to PMBJP during 2017-18, the Government released Rs. 47.64 core to BPPI for implementing the scheme throughout the country including 'North Eastern States'. The increased allocation in the MH 2552 for North Eastern Area is no doubt, the additional financial assistance for NE States which will help functional PMBJP Kendra's in NE States to attain business sustainability by fulfilling the main objective of the scheme i.e. to make available quality generic medicines at affordable price to all.

As on 31.3.2018, 3322 PMBJP Kendras were functional in 33 States/UTs of the country out of which 158 were functional in North Eastern States. A state-wise list of 158 functional PMBJP in NE states, is as under:

Sl. No.	**North Eastern States**	**Number of PMBJP Kendras**
1	Arunachal Pradesh	24
2	Assam	52
3	Manipur	36
4	Meghalaya	1
5	Mizoram	8
6	Nagaland	11
7	Sikkim	2
7	Tripura	24
	Total	**158**

As on 28.05.2018, 3600 PMBJP Kendras are functional in 34 States/UTs of the country out of which 165 PMBJP Kendras are functional in North Eastern States. A State-wise list of 165 PMBJP Kendras in NE States, is as under:

Sl. No.	North Eastern States	Number of PMBJP Kendras
1	Arunachal Pradesh	24
2	Assam	59
3	Manipur	35
4	Meghalaya	1
5	Mizoram	9
6	Nagaland	13
7	Sikkim	2
7	Tripura	22
	Total	**165**

Comments of the Committee

(Please see Para No.7 of Chapter- I of the Report)

Recommendations (Sl. No. 4)

The Committee note that in the backdrop of the changing scenario in the pharma sector and the recommendations of various committees, the ongoing central sector scheme has been re-named as "Scheme of Consumer Awareness & Publicity and Print Monitoring" from 2015-16 onwards. As per approval of the Standing Finance Committee this scheme has 2 components, a central component and a state component. The central component includes the joint publicity campaign by the NPPA and Department of Consumer Affairs on a 50:50 cost sharing basis. The state component of the scheme comprises setting up of Price Monitoring and Resource Units (PMRUs) An amount of Rs. 5.45 crores was provided in BE (2016-17) which has been reduced to Rs. 2.87 crores under RE (2016-17) for the Scheme and actual expenditure was Rs 2.17 crores. Further the Committee note that during the year 2017-18 Rs. 4 crores were allocated at BE stage for modified scheme-Consumer Awareness, Publicity and Price Monitoring, which remained unaltered at RE stage however, expenditure could not be incurred due to issues related to opening of a separate Head for the Plan Scheme of Consumer Awareness, Publicity and Price Monitoring with certain sub-heads, and obtaining 15 digit numeric head for the Scheme.

Now in 2018-19 again Rs.4 crores has been allocated. The Committee note that the objectives of setting up the PMRUs are to provide necessary technical

assistance to the State Drug Controllers and NPPA towards monitoring the notified prices of medicines, detection of violation of the provisions of DPCO, pricing compliance and ensuring availability of medicines, monitoring the price movement of scheduled and non-scheduled formulations, collection and compilation of market based data of scheduled and non-scheduled formulations, collection of test samples of medicines from the retail market whenever required and conduct of training, seminars and workshops at the State and District levels for consumer awareness and publicity.

The Committee further note that this scheme was modified to cater to the requirement of payment for setting up of Price Monitoring and Resource Units (PMRU). The Modified scheme under approval envisaged creation of PMRUs in seven States viz. Maharashtra, Gujarat, Orissa, Haryana, Kerala, Assam and Manipur on pilot basis. However, subsequently, this was limited to four States *viz*. Kerala , Gujarat, Odisha and Maharashtra and as such no time limit has been fixed. Under the revised scheme, PMRU is proposed to be a registered society under the Chairmanship of the State Drugs Controllers with representatives from NPPA, Health Department of the State Government and of Civil Societies. DO letters were sent by Chairman NPPA to Secretary (Health) of Kerala, Gujarat and Odisha for creation of societies enabling NPPA to release funds to these states after the approval of the modified scheme from Department of Pharmaceuticals. The creation of the Society as proposed in the Scheme in the respective states would enable early release of funds by NPPA.

The Committee would like the Department to convince each State and UT to have PMRU so that they can extend all necessary support to the State Drug Controllers in carrying out monitoring and enforcement activities under the Drug Price Control Order, 2013 in their respective jurisdictions, which as on date is not up to the mark. As a result of this Indian drug market is adulterated with spurious and expired drugs. PMRUs once established will also ensure that the benefits of the DPCO trickle down to the grassroots level, which is the need of the hour. Thus, the Committee recommend the Department to work in close coordination with NPPA, State Drugs Controllers, State Health Department and likeminded Civil society representatives where PMRUs are being implemented on pilot basis. Thereafter based on the success of these pilot projects the scheme should be implemented in other states/UT within a fixed timeframe**.**

Reply to the Government

During the year 2017-18, out of the RE of Rs. 2.00 crore, an amount of Rs. 6.43 lakhs was released under central component. No amount could be incurred for setting up of Price Monitoring and Resource Units (PMRU), as there was no separate Head for the Scheme of Consumer Awareness, Publicity and Price Monitoring.

For the year 2018-19, Rs. 4.00 crore has been allocated for the scheme. Government has since approved the modified scheme 'Consumer Awareness, Publicity and Price Monitoring' on 17.04.2018. The scheme will be implemented at Central level by NPPA and at the State level by registered societies of Price Monitoring & Resource Units (PMRUs).

Budget head for the scheme has also been opened. The modification in the scheme has been done to cater to the requirement of payment for setting up of Price Monitoring and Resource Units (PMRU). Under the revised scheme, PMRUs is proposed to be a registered society under the Chairmanship of the State Drugs Controllers. NPPA has requested the State Governments of Kerala, Gujarat and Odisha for creation of societies. The creation of the society as proposed in the scheme in the respective States would enable early release of funds by NPPA in order to achieve the objectives of the scheme.

The committee's recommendations in respect of working of DoP in close coordination with NPPA and other stakeholders has been noted for compliance.

Comments of the Committee

(Please see Para No.13 of Chapter- I of the Report)

Recommendations Sl. No. 6

The Committee note that the Department initiated setting up of National Centre for R&D in Bulk Drug (NCRDBD), in order to promote inter-linkages with the industry at the allocated site of NIPER-Hyderabad at Genome Valley of Medak District. Standing Finance Committee (SFC) has approved Rs.54.20 crores in 2014 for this purpose. However, Rs. 12 crores was actual utilization under this scheme in 2015-16. During the year 2016-17 and 2017-18 only Rs 0.01 crores has been allocated but there is nil actual utilization in both the years. In the year 2018-19 as well no allocation has been done under this scheme. The Committee note that the first and foremost challenge is availability of cheaper imported Active Pharmaceutical Ingredients (APIs) after globalization, which has badly hit the indigenous bulk drug development & industry. The Committee further note that the bulk drug industry is highly polluting and its effluents are highly hazardous, whose treatment adds to the cost of production. For this the government has started a scheme for assistance to Bulk Drug Parks in which Govt. will fund the common facility including Effluent Treatment Plants. The Standing Finance Committee (SFC) has Further approved Assistance to Bulk Drug Industry for Common Facilitation Centre on 7.2.2018. The Committee recommend the Department to swiftly utilize the allocated funds under this scheme for Bulk Drug industry. The Committee also note that inverted duty structure is also adversely impacting the bulk drug production sector and recommend the Department to address the major

issue of inverted duty structure so that import of bulk drugs can be checked and domestic bulk drug industry is made competitive and sustainable.

Reply of the Government

An Memorandum of Understanding (MoU) was signed between National Projects Construction Corporation Ltd (NPCC) and NIPER Hyderabad for Setting up National Centre for R&D in Bulk Drug (NCRDBD) with project outlays for Rs. 54.20 crore after approval of Standing Finance Committee (SFC). Accordingly, Rs.12.00 crore were released during FY 2015-16. Since the construction of NIPER Hyderabad campus has been delayed due to scarcity of funds, the activity for establishment of NCRDBD could not be initiated. NIPER Hyderabad has been requested to return unutilized funds to Government.

Department of Pharmaceuticals had recommended to Ministry of Finance correction of Inverted Duty Structure in Pharmaceuticals Industry. Ministry of Finance vide notification No. 6/2016-Customs dated 28.1.2016 withdrew the Custom Duty exemptions granted to certain categories of drugs/bulk drugs.

Comments of the Committee

(Please see Para No. 19 of Chapter- I of the Report)

CHAPTER – V

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT ARE STILL AWAITED

NIL

New Delhi;
27 July, 2018
05 Shravana 1940 (Saka)

ANANDRAO ADSUL
Chairperson,
Standing Committee on Chemicals and Fertilizers

Appendix- I

MINUTES OF THE FOURTEENTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2017-18)

The Committee sat on Monday, the 23 July, 2018 from 1500 hrs. to 1530 hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT

Shri Anandrao Adsul - Chairperson

MEMBERS

LOK SABHA

2. Shri George Baker
3. Smt. Anju Bala
4. Shri Sankar Prasad Datta
5. Smt. Veena Devi
6. Shri K. Ashok Kumar
7. Shri S. Rajendran
8. Smt. Kamla Devi Patle
9. Dr. Kulamani Samal
10. Smt. Rekha Arun Verma
11. Dr. Prof. Seetaram Naik

RAJYA SABHA

12. Dr. Sanjay Sinh
13. Shri Ranvijay Singh Judev
14 Shri Vijay Pal Singh Tomar

SECRETARIAT

1. Shri Vinod Kumar Tripathi - Joint Secretary
2. Shri A. K. Srivastava - Director
3. Shri U. C. Bharadawaj - Deputy Secretary

2. At the outset, the Hon'ble Chairperson welcomed the Members of the Committee.

3. The Committee thereafter took up for consideration and adoption the following draft Reports:

(i) Draft Report on the subject 'Assam Gas Cracker Report' of the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals)

(ii) Draft Report on Action taken Replies by the Government on the Observations/ Recommendations contained in the Forty First Report of the Standing Committee on Chemicals and Fertilizers (16th Lok Sabha) on the subject 'Freight Subsidy Policy' of the Ministry of Chemicals and Fertilizers (Department of Fertilizers);

(iii) Draft Report on Action taken replies by the Government on the Observations/ Recommendations contained in the Forty Fifth Report of the Standing Committee on Chemicals and Fertilizers (16th Lok Sabha) on 'Demand for Grants (2018-19)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

(iv) Draft Report on Action taken replies by the Government on the Observations/ Recommendations contained in the Forty Fourth Report of the Standing Committee on Chemicals and Fertilizers (16th Lok Sabha) on 'Demand for Grants (2018-19)' of the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals).

4. After deliberations the Draft Reports were adopted by the Committee. without any changes/amendments.

5. The Committee authorised the Chairperson to make consequential changes, if any, arising out of the factual verification of the Reports by the Department of Fertilizers, Department of Pharmaceuticals and Department of Chemicals and Petrochemicals.

The Committee then adjourned.

Appendix – II

(*Vide* Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FORTY FIFTH REPORT (SIXTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2018-19) ON 'DEMANDS FOR GRANTS (2018-19)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

S. No.	Total No. of Recommendations	9
I	Observations / Recommendations which have been accepted by the Government: (*Vide* Recommendation Nos. 1,3,5,7,8)	5
	Percentage of Total	56 %
II	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation Nos. 9)	1
	Percentage of Total	11 %
III	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (*Vide* Recommendation Nos. 2,4,6)	3
	Percentage of Total	33 %
IV	Observations / Recommendations in respect of which final replies of the Government are still awaited: Nil	0
	Percentage of Total	0%